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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,232

06/19/2006

Young Min Kim

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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SUITE 5400

SEATTLE, WA 98104

EXAMINER

OUSPENSKI, ILIA I

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,232	Applicant(s) KIM ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 12, 20-26 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-19, 27-37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and remarks, filed on 08/04/2008, are acknowledged.

Claims 1 – 45 are pending.

Claims 20 – 26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 04/22/2008.

2. Applicant's election of the following species in the reply filed on 08/04/2008 is acknowledged: aldehyde group as reactive group; PEG as non-peptide polymer; and erythropoietin as physiologically active polypeptide.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12 and 38 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1 – 11, 13 – 19, 27 – 37, and 39 – 45 are presently under consideration.

3. Receipt is acknowledged of foreign priority papers (Application No. 10-2003-0080299, Republic of Korea) submitted under 35 U.S.C. 119(a)-(d), which papers are of record in the file of the instant application.

4. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 11, 13 – 19, 27 – 37, and 39 – 45 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 – 11, 13 – 19, 27 – 37, and 39 – 45 are indefinite in the recitation of fragments which are covalently linked to “one” in claim 1, because the identity of the entity denoted by the word “one” is unknown. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

B. Claims 13 and 39 are indefinite in the recitation of “a reactive aldehyde group,” because the recitation lacks proper antecedent basis in the respective base claims 12 and 38.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

6. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 1, 4 – 10, 14 – 18, 27, 30 – 36, and 40 – 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Pettit (US Patent No. 6,441,136; of record; see entire document).

Pettit (US Patent 6,441,136) teaches a protein conjugate comprising TNF receptor covalently linked to Fc region and non-peptide polymer such as PEG (e.g. see Example 3 at columns 12-13). One of skill in the art is aware that TNF receptor is a physiologically active peptide and an interleukin receptor. Pettit also teaches various methods of conjugating PEG to polypeptides (e.g. columns 6 – 7) and pharmaceutical compositions comprising the protein conjugate (e.g. Example 5 at column 14).

Therefore, the teachings of the reference anticipate the instant claimed invention.

8. Claims 1 – 11, 13 – 19, 27 – 37, and 39 – 45 are rejected under **35 U.S.C. 102(e)** as being anticipated by DeFrees et al. (US Patent No. 7,125,843; see entire document).

DeFrees et al. teach conjugates comprising a peptide and an agent covalently linked via a linker (see e.g. the diagram at column 67). The agent may be an antibody (e.g. column 67 line 48), which inherently comprises an immunoglobulin Fc fragment, and the linker may be PEG (e.g. column 68 line 30), which may be conjugated via an aldehyde group. The peptide may be a biologically active polypeptide, including erythropoietin (e.g. Scheme 3 at columns 71 – 72, and Table 6 at column 190). DeFrees et al. further teach pharmaceutical compositions comprising the conjugates (e.g. Figure 136 and description of the figure at column 30).

Therefore, the teachings of the reference anticipate the instant claimed invention.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 – 11, 13 – 19, 27 – 37, and 39 – 45 are provisionally rejected on the ground of nonstatutory obviousness-type **double patenting** as being unpatentable over claims 1 – 13 of copending Application No. 10/535231, published as US Pat. Pub. No. 2006/0275254. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same or nearly the same polypeptide conjugates and compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. The instant claims are directed to an invention not patentably distinct from the claims of commonly assigned Application No. 10/535231, for the reasons addressed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned application, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were

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commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. Conclusion: no claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/

ILIA OUSPENSKI, Ph.D.

Primary Examiner

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November 11, 2008